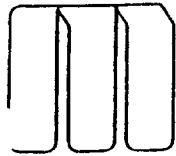


K957905



Minimatic
Implant
Systems

"Tomorrow's Technology Today"

APR 16 1997

June 23, 1995

FDA
LOU HLAVINKA HFZ-410
DEVICE CONTROL
9200 CORPORATE BLVD
ROCKVILLE, MD 20856

510K Summary

RE: 510K REVIEW AND UPDATE.

Minimatic attests that:

1. Minimatic is the designer, manufacturer, and marketer of the enclosed devices.
2. The devices are Dental devices that currently are classified in Class III.
3. The devices are substantially equivalent to devices currently being marketed.
4. The devices in and of themselves are considered safe and effective provided that the devices are utilized as intended.